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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------------|
| 10/633,402 | 08/01/2003 | V. Suzanne Klimberg | 781.020US1 | 6071 |
| 21186 7590 08/13/2008 SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402 | | | EXAMINER ANDERSON, JAMES D | |
| | | | ART UNIT 1614 | PAPER NUMBER |
| | | | MAIL DATE 08/13/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/633,402

Applicant(s)

KLIMBERG ET AL.

Examiner

JAMES D. ANDERSON

Art Unit

1614

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 June 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 6-10-14-44-53-55 and 56.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

/James D Anderson/
Examiner, Art Unit 1614

Continuation of 11, does NOT place the application in condition for allowance because: The Examiner has carefully considered Applicant's response filed 6/24/2008 but is not persuaded that the claimed method is unobvious over the cited prior art. Applicants argue that Wilmore does not teach administration of glutamine to protect against breast or upper body tissue damage from radiation therapy administered to breast cancer patients. However, Wilmore clearly and unequivocally teaches that administration of glutamine can ameliorate or prevent radiation-associated oxidative damage in the tissue (Abstract; col. 2, lines 46-57; col. 5, line 58 to col. 6, line 2), specifically teaching, suggesting, and motivating administration of glutamine or a glutamine equivalent before, during, and/or after chemotherapy or RADIATION TREATMENT (col. 5, lines 62-64), thereby alleviating the tissue-damaging effect of free radicals generated during treatment by this administration of glutamine (col. 5, line 67 to col. 6, line 2). Applicant further argues that the method of Wilmore is not intended to be practiced by oral administration of glutamine. However, Wilmore teaches that glutamine CAN be administered orally (col. 6, lines 22-48), regardless of the fact that such oral administration is focused on treatment of poisoning. Further, Shinal et al. also teach the oral administration of glutamine and a carbohydrate. As such, the skilled artisan would have been imbued with at least a reasonable expectation that oral administration of glutamine would be therapeutically effective for alleviating the tissue-damaging effects of free radicals generated during radiation treatment. With regard to Shinal et al., while the disclosure of Shinal et al. is directed to the administration of glutamine and carbohydrate compositions to prevent or treat oral, nasal and esophageal lesions, Shinal et al. is provided as motivation to add a carbohydrate to the glutamine treatment methods of Wilmore et al., not for the claimed tissue protecting effects of glutamine, which are taught by Wilmore. Good et al. is simply provided as evidence that radiation treatment is often used in the treatment of breast cancer, thus providing the motivation to use the treatment methods taught, suggested, and motivated by Wilmore and Shinal in breast cancer patients receiving radiation therapy. With respect to Applicant's arguments that the present invention fulfills a "long-felt need", the cited web pages only teach what is well known in the art - that radiation therapy has side effects. However, Wilmore teaches a method of alleviating the tissue-damaging effects of free radicals generated during radiation therapy, thus fulfilling the need to reduce at least one side effect of radiation therapy. Applicant's discovery of another potential benefit of the treatment methods suggested and motivated by the cited prior art is not seen as a patentable distinction over the cited references.